

**REMARKS**

Claims 1-8 and 10 are pending in the application. Claim 6 has been amended. Claim 9 has been canceled.

In view of the following remarks, reconsideration and withdrawal of the rejections to the application in the Office Action is respectfully requested.

***I. Rejection of Claims 6-10 under 35 U.S.C. § 112, second paragraph.***

In the Office action the Examiner rejected Claims 6-10 under 35 U.S.C. § 112, second paragraph, as indefinite, alleging that the use of the terms “*in vitro*” and “*ex vivo*” in Claim 6 is confusing since both terms have the same meaning. Claim 6 has been amended to remove the term “*ex vivo*”. In light of this amendment Applicant respectfully submits that this rejection has been overcome and respectfully requests its withdrawal.

***II. Rejection of Claims 1-4 under 35 U.S.C. § 102(a).***

Claims 1-4 were rejected by the Examiner under 35 U.S.C. § 102(a), as anticipated by Indig, J. Pharm. Sci., Jan. 2000. Applicant respectfully traverses.

Applicant respectfully directs the Examiner’s attention to the Declaration of Guilherme L. Indig which is submitted under 37 C.F.R. § 1.132 (hereinafter “the Indig Declaration”). Applicant hereby requests that the Indig Declaration be entered in the file of this application and be made of record. The Indig Declaration was initially submitted during the prosecution of the parent application (U.S. Patent Application Serial No. 09/753,472) in an Amendment and Reply under 37 C.F.R. § 1.116, mailed on September 26, 2003. In an Advisory Action mailed on November 6, 2003, in response to the above-referenced Amendment and Reply, the Examiner acknowledged that the Indig Declaration successfully removed Indig, J. Pharm. Sci., Jan. 2000 as prior art to the pending claims.

The Indig Declaration establishes the following: Guilherme L. Indig, Gregory F. Anderson, Michael G. Nichols, Jeremy A. Bartlett, William S. Mellon, and Fritz Sieber are co-authors of the article entitled, "Effect of Molecular Structure on the Performance of Triarylmethane Dyes as Therapeutic Agents for Photochemical Purging of Autologous Bone Marrow Grafts from Residual Tumor Cells," published in The Journal of Pharmaceutical Sciences, Vol. 89, No. 1, January 2000 (and referred to in the Office Action as "Indig, J. Pharm. Sci., Jan. 2000"). This article was published prior to, but not more than one year before, the filing date of the present application. The enclosed declaration of Guilherme L. Indig confirms that although other authors are listed on the article, Dr. Indig is the sole inventor of the subject matter claimed in the present application. For this reason, Indig, J. Pharm. Sci., Jan. 2000 is not prior art that can be asserted against the claims of this application.

Because Indig, J. Pharm Sci., Jan. 2000, is not prior art to the pending claims, Applicant respectfully requests that this rejection be withdrawn.

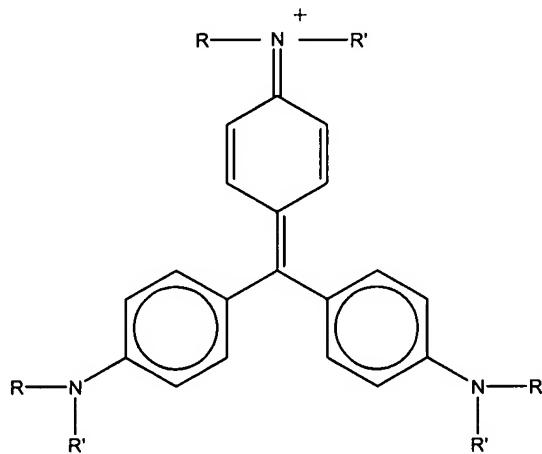
Applicant has also enclosed the cover page for J. Pharm. Sci., Jan. 2000, showing that the journal was not mailed out until the week of January 31, 2000. Applicants have also enclosed a copy of a webpage from the Wiley InterScience website, showing that Indig, J. Pharm. Sci., Jan. 2000, was not published on the web until February 7, 2000. These enclosures establish that Indig, J. Pharm Sci., Jan. 2000, was not published more than one year prior to the priority date of this application.

***III. Rejection of Claims 1, 2 and 4-10 under 35 U.S.C. § 102(b).***

Claims 1, 2 and 4-10 were rejected under 35 U.S.C. § 102(b) as anticipated by Fiedorowicz et al. In support of this rejection the Examiner asserted that Fiedorowicz et al., discloses a method of purging leukemia cells from a mixture containing human blood cells by contacting the mixture with the compound of the instant claims and exposing it to radiation to photoactivate the compound. Applicant respectfully traverses.

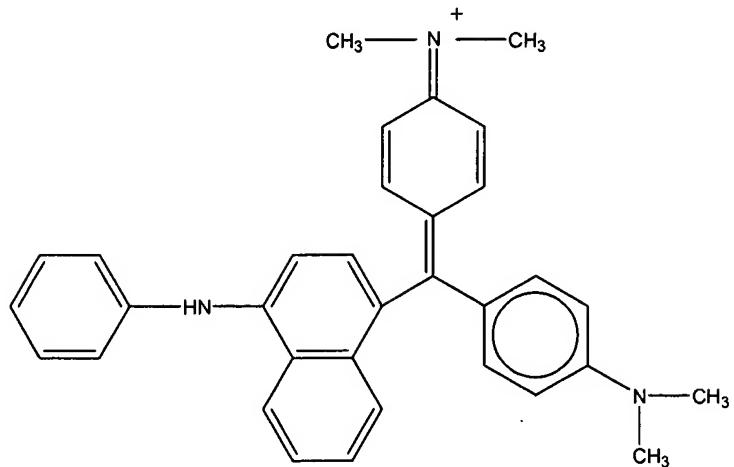
In order to establish a *prima facie* case of anticipation, a cited reference must disclose each and every limitation of the rejected claim. (MPEP 2131) Fiedorowicz et al., fails to provide a *prima facie* case of obviousness, because Fiedorowicz et al. does not disclose a method of purging malignant cells or a method of killing cancer cells by contacting the cells with the compound recited in the rejected claims.

Independent Claim 1 recites a method of purging malignant cells from a mixture containing malignant and non-malignant cells by contacting the mixture with the following compound:



wherein each *R* and *R'* is independently selected from the group consisting of hydrogen and C<sub>1</sub>-C<sub>6</sub> linear or branched alkyl. Similarly, independent Claim 6 recites a method of killing cancer cells or inhibiting the growth of cancer cells by contacting the cancer cells with the compound shown above. In contrast, Fiedorowicz et al. describes the photodynamic effect of Victoria Blue

BO on peripheral blood mononuclear cells. Victoria Blue BO has the following structure:



A comparison of the Victoria Blue BO structure with the structure recited in rejected Claims 1 and 6 clearly shows that the structures are not the same. Thus, contrary to the Examiner's assertion, Fiedorowicz et al., does not describe a method of purging leukemia cells from human blood cells by contacting the cells with the compound recited in the rejected claims. Therefore, Fiedorowicz fails to teach each and every limitation of the rejected claims and Applicant respectfully requests that this rejection be withdrawn.

***IV. Rejection of Claim 5 under 35 U.S.C. § 103(a).***

Claim 5 was rejected under 35 U.S.C. § 103(a) as unpatentable over Indig, J. Pharm. Sci., Jan. 2000, in view of Cancer Medicine, 6<sup>th</sup> Edition. Applicants respectfully traverse. For the reasons presented in Section II. above, Applicants note that Indig, J. Pharm. Sci., Jan. 2000, is not prior art to the pending claims. For this reason, the Applicant respectfully requests that this rejection be withdrawn.

***V. Rejection of Claims 1-10 under 35 U.S.C. § 103(a).***

Claims 1-10 were rejected under 35 U.S.C. § 103(a), as unpatentable over Indig, Res. Devel. Pure & Applied Chem., 1999 in view of Indig, J. Pharm. Sci., Jan. 2000. Applicant respectfully traverses.

For the reasons described in Section II. above, Applicant notes that Indig, J. Pharm. Sci., Jan. 2000, is not prior art to the pending claims. In addition, Applicant respectfully directs the Examiner's attention to the Declaration of S. G. Pandalai, submitted under 37 C.F.R. § 1.132 (hereinafter "the Pandalai Declaration"). As stated in the Pandalai Declaration, S. G. Pandalai is the managing editor of Transworld Research Network, the publishers of the book Recent Research and Development in Pure and Applied Chemistry, Vol. 3 (1999) (referred to in the Office Action as "Recent Res. Devel. Pure & Applied Chem. 1999"). As further stated in the Pandalai Declaration, although the book Recent Research and Development in Pure and Applied Chemistry, Vol. 3 (1999), bears a publication year of 1999, it was actually first published in March of 2000. In view of these facts, Applicant respectfully submits that Indig, Recent Devel. Pure & Applied Chem., 1999 is not prior art to the rejected claims and requests that this rejection be withdrawn.

***VI. Double Patenting Rejection.***

Claims 1-10 were rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over Claims 1-9 of U.S. Patent No. 6,914,078. As noted in the Office Action, a Terminal Disclaimer may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground.

Enclosed is a timely filed Terminal Disclaimer in compliance with 37 C.F.R. § 1.321(c) and 37 C.F.R. § 3.73(b). It is respectfully submitted that the Terminal Disclaimer submitted herewith overcomes the rejections of Claims 1-10. Therefore, Applicant respectfully requests that the Examiner withdraw the rejection of Claims 1-10 based on nonstatutory obviousness-type double patenting and allow this application to issue. The filing of the enclosed Terminal

Disclaimer should not be construed as an admission by the Applicant that the rejection of claims 1-10 under the judicially created doctrine of obviousness-type double patenting is appropriate.

***VII. Information Disclosure Statement.***

In the Office Action the Examiner stated that the following references could not be located in the present file or in the file for the parent application:

- (1) Dyer, H. M., *An Index of Tumor Chemotherapy*, NIH. August 13, 1951, pp. 10-12, 123 and 124;
- (2) Foote, C. S., "Definition of type I and type II photosensitized oxidation." *Photochem. Photobiol.*, Vol. 54, No. 5, p. 659, 1991; Pergamon Press pic, printed in Great Britain;
- (3) Indig, G. L., "Photochemistry of triarylmethane dyes bound to proteins." *Proceedings of Optical Methods for Tumor Treatment and Detection: Mechanisms and Techniques in Photodynamic Therapy V*, Vol. 2675, pp. 228-237, 1996, Society of Photo-Optical Instrumentation Engineers; and
- (4) Patel, J. et al., "Design of Novel Analogs of Victoria Blue BO (VBBO) for Photodynamic Theraphy." *Abstracts of Papers of the American Chemical Society*, Vol. 203, april 5-10, 1992, San Francisco, California.

Applicant has enclosed a copy of each of these references in this communication. Another copy of the Information Disclosure Statement filed on May 17, 2004 is also enclosed. Applicant respectfully requests that the Examiner initial the enclosed copy of the Information Disclosure Statement filed on May 17, 2004, acknowledging receipt and review of these references, and further requests that the initialed copy of the Information Disclosure Statement be made of record.

In view of the foregoing remarks Applicant respectfully submits that all the claims remaining in the application are condition for allowance and favorable action thereon is respectfully solicited. The Examiner is invited contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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